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Lafontaine

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(54) **CRYOTREATMENT DEVICES AND METHODS OF FORMING CONDUCTION BLOCKS**

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A61B 18/02 (2006.01)

(52) **U.S. Cl.**
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(58) **Field of Classification Search**
CPC A61B 18/02; A61B 2018/0212; A61B 2018/0262; A61B 2018/0293
See application file for complete search history.

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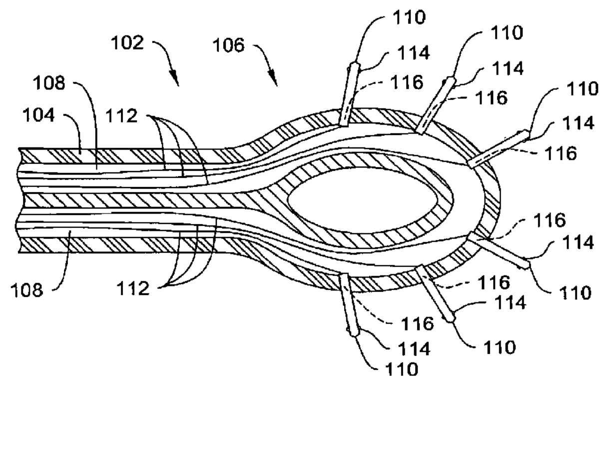
(57) **ABSTRACT**

Cryotreatment devices and methods of ablating tissue within the body are disclosed. A cryotreatment device in accordance with an exemplary embodiment of the present invention includes an elongated member having one or more needle-like ablation tips configured to induce necrosis at a target site within the heart. A cooling fluid such as a cryogen may be injected through a lumen extending into the distal portion of the device. The ablation tips can be configured to pierce and ablate surrounding tissue, blocking electrical stimuli that can cause fibrillations or other arrhythmias of the heart. The device may also include means for controlling the transmural depth at which the ablation tips are inserted into the cardiac tissue. Methods of forming a contiguous line of conduction block in accordance with the present invention are also disclosed.

20 Claims, 4 Drawing Sheets



Related U.S. Application Data

continuation of application No. 12/485,697, filed on Jun. 16, 2009, now Pat. No. 8,048,066, which is a division of application No. 10/411,601, filed on Apr. 10, 2003, now abandoned.

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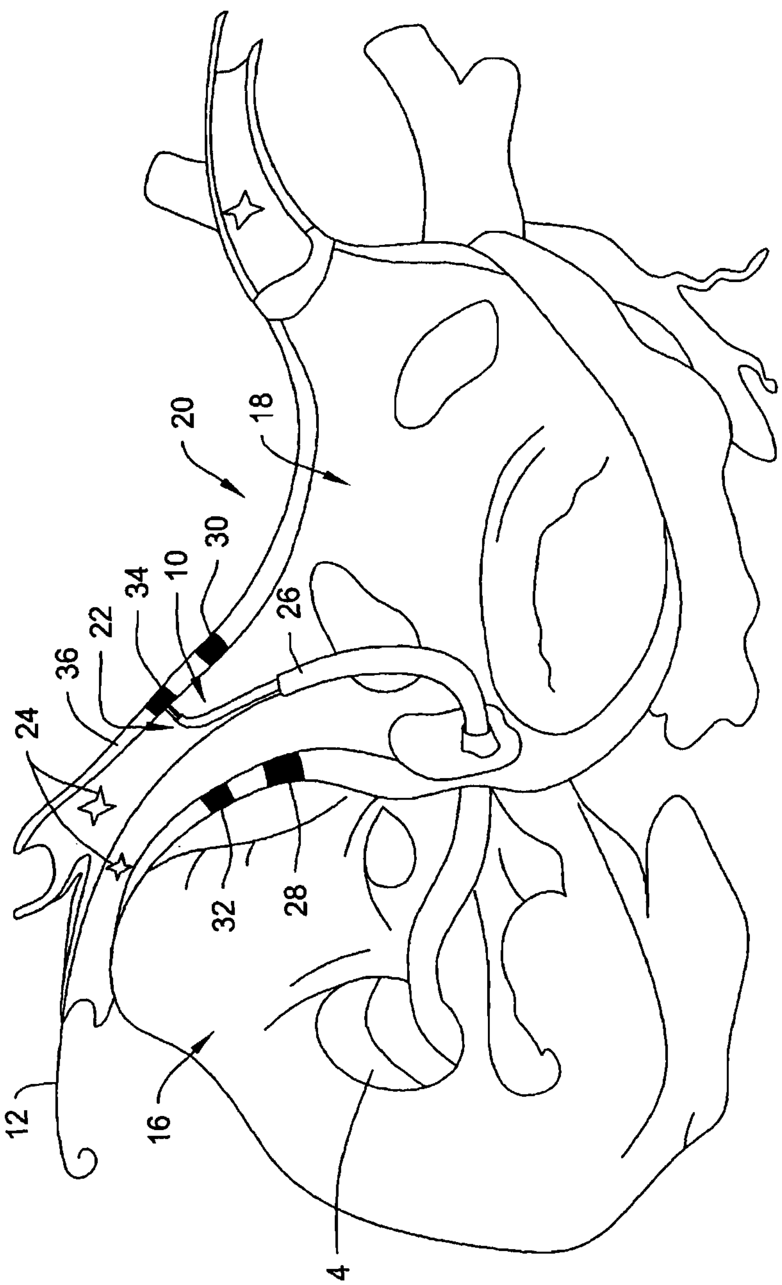

Fig.1

Fig.2

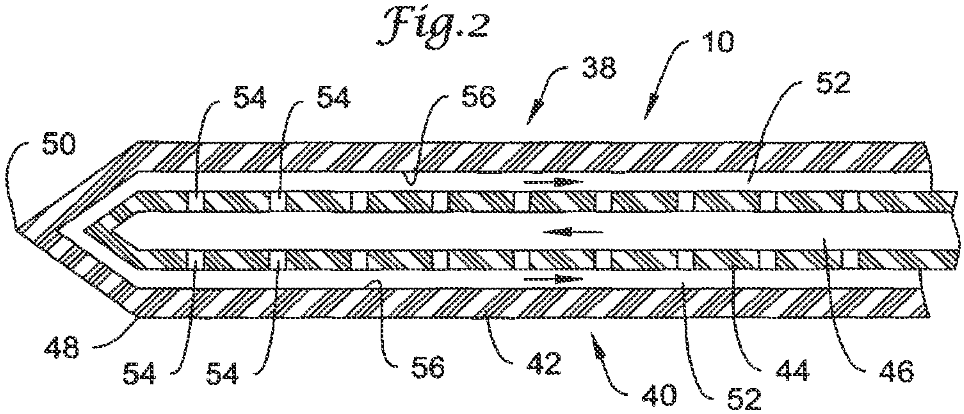
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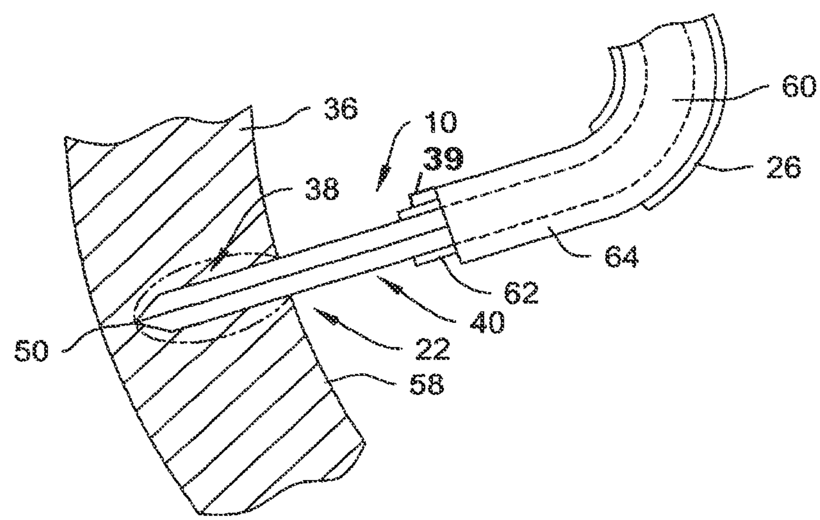
Fig.3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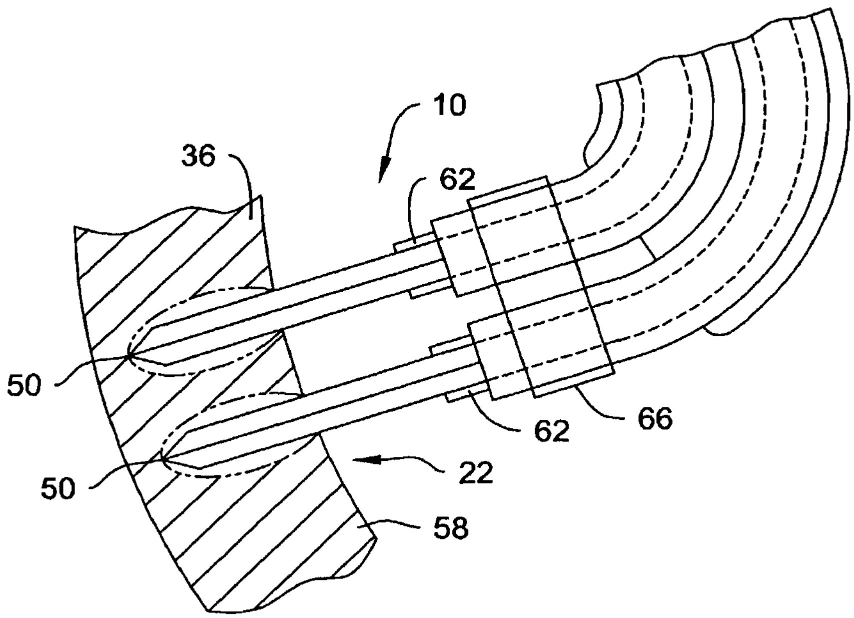

Fig.4

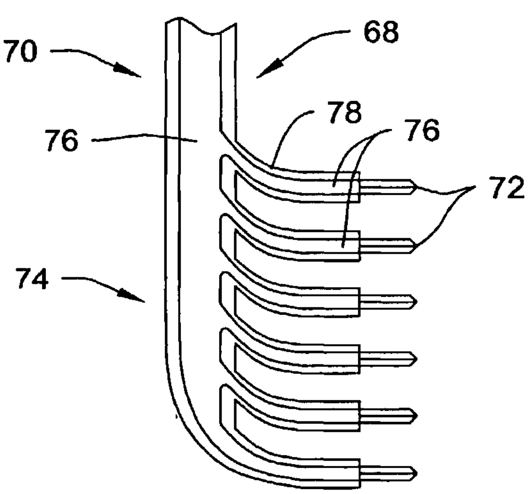

Fig.5

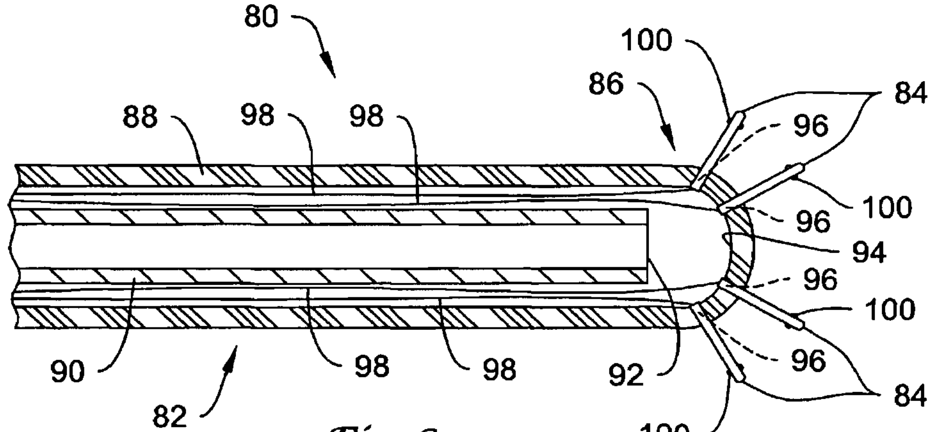
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Fig.6

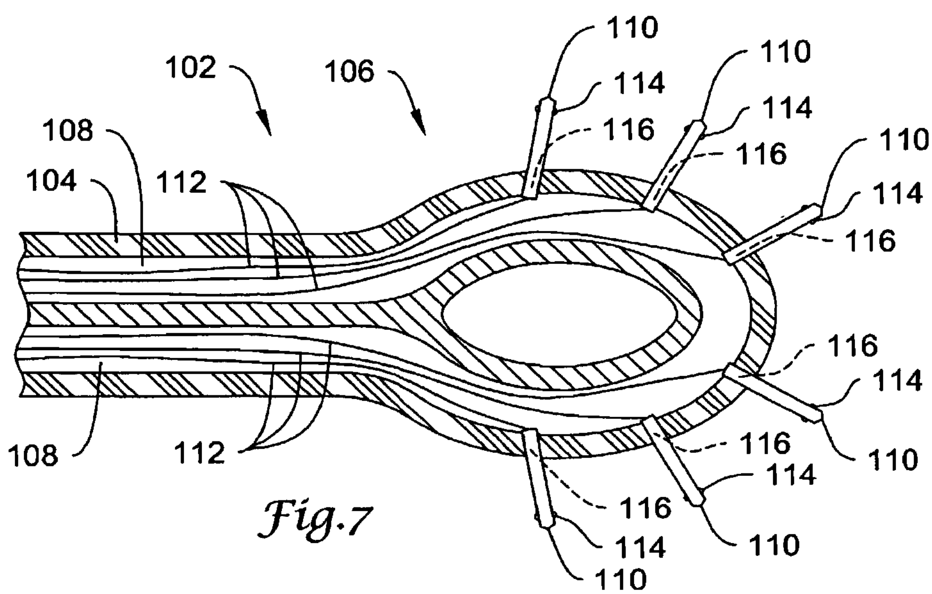
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Fig.7

CRYOTREATMENT DEVICES AND METHODS OF FORMING CONDUCTION BLOCKS

CROSS-REFERENCE TO RELATED APPLICATIONS

This application is a continuation of U.S. application Ser. No. 14/084,257, filed Nov. 19, 2013, now U.S. Pat. No. 9,033,967; which is a continuation of U.S. application Ser. No. 13/252,817, filed Oct. 4, 2011, now U.S. Pat. No. 8,585,689; which is a continuation of U.S. application Ser. No. 12/485,697, filed Jun. 16, 2009, now U.S. Pat. No. 8,048,066; which is a divisional of U.S. application Ser. No. 10/411,601, filed Apr. 10, 2003, now abandoned, the entire disclosures of which are all incorporated herein by reference.

FIELD OF THE INVENTION

The present invention relates generally to medical devices for ablating tissue at one or more target sites. More specifically, the present invention relates to cryotreatment devices and methods for inducing controlled necrosis of cardiac tissue within the heart.

BACKGROUND OF THE INVENTION

Cardiac arrhythmias such as atrial fibrillation, bradycardia, ventricular tachycardia, ventricle fibrillation, and Wolff-Parkinson-White syndrome are common heart abnormalities that cause stroke, myocardial infarction, and other thromboembolic events within the body. In patients with normal sinus rhythm, the heart is electrically excited to beat in a synchronous and patterned manner, typically at a rate of 60 to 100 beats per minute (bpm). In contrast, in patients with cardiac arrhythmia, abnormal regions of the cardiac tissue may aberrantly conduct to adjacent tissue, causing the heart to beat irregularly. In ventricular tachycardia, for example, electrical signals may be errantly received in the lower heart chamber (i.e. the ventricle) instead of the right, upper chamber (i.e. the atria), causing the heart to beat rapidly. In atrial fibrillation, the most common type of cardiac arrhythmia, the upper chambers of the heart beat at an uncontrolled rate of 350 to 600 bpm, which results in a reduction of the pumping force of the heart. As a result of this reduced pumping force, blood in the heart chambers may become stagnant and pool, forming blood clots that can dislodge within the body and cause stroke or other life threatening events.

To treat cardiac arrhythmia, a number of therapeutic procedures have been developed, including RF catheter ablation, chemical cardioversion, percutaneous myocardial revascularization (PMR), and suppression. Antiarrhythmic medications such as beta-blockers, calcium channel blockers, anticoagulants, and DIGOXIN have also been used successfully to treat some forms of cardiac arrhythmia. More recent trends have focused on the use of cryotreatment catheters to treat arrhythmias such as atrial fibrillation and ventricular tachycardia. Such devices provide a relatively non-invasive method of treatment in comparison to other surgical techniques.

In one such method, for example, a catheter loaded with a cryogenic cooling fluid may used to cryogenically cool cardiac tissue at strategic locations of the heart, such as the right and left atria, or the pulmonary veins. The catheter can be used to induce necrosis at one or more pre-mapped target sites within the heart to create conduction blocks within the aberrant electrical conduction pathways. In atrial fibrillation, for example, necrosis of one or more target sites within the atrial cardiac muscle tissue can be used to block the electrical signals believed to cause and/or sustain the fibrillation.

In some techniques, the use of a cryotreatment device to form the required conduction block may be ineffective since there is no adequate means to control the transmural depth of the lesion, or the distance between each lesion. To compensate for these shortcomings, many cryotreatment devices utilize relatively large catheter tips, which destroy more tissue than is necessary to form the conduction block and further reduce the already weakened pumping force of the heart. It is therefore desirable to have a cryotreatment device capable of transmurally controlling the depth of each lesion and in a contiguous manner.

SUMMARY OF THE INVENTION

The present invention relates generally to cryotreatment devices and methods for reducing or eliminating arrhythmia by inducing controlled necrosis at one or more pre-mapped target sites within the heart. A cryotreatment device in accordance with an exemplary embodiment of the present invention may comprise an elongated member having a proximal portion, a distal portion, and one or more lumens therein in fluid communication with a cooling fluid adapted to cool the distal portion of the elongated member. The elongated member may include one or more needle-like ablation tips configured to pierce and necrotize cardiac tissue within the heart, preventing the conduction of aberrant electrical signals through the tissue to one or more relay sites of arrthymogenic foci. The cryotreatment device may include one or more features configured to form an array of ablations within the cardiac tissue, forming a contiguous line of conduction block.

The ablation tips may be retractable within the elongated member to control the penetration depth of the tips transmurally into the cardiac tissue. A pull cord operatively coupled to the ablation tip can be used to retract the ablation tip from the cardiac tissue. An ultrasonic probe or other measuring device may also be provided to measure and control the insertion depth of the cryotreatment device within the cardiac tissue.

A cryosurgical method in accordance with the present invention may comprise the steps of providing a cryotreatment device to a target site within the heart, and necrotizing one or more locations within the cardiac tissue to form a contiguous line of conduction block. A cooling fluid such as liquid nitrous oxide can be injected through an inner lumen extending to the distal portion of the cryotreatment device to cool the surrounding tissue adjacent the ablation tips.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is an illustration of a cryotreatment device in accordance with an exemplary embodiment of the present invention, wherein the device is shown inserted through the septal wall of the heart and advanced to a target site at or near one or more relay points;

FIG. **2** is a partial cross-sectional view of the cryotreatment device of FIG. **1**;

FIG. **3** is a detailed view of the cryotreatment device of FIGS. **1**-**2**, wherein the device includes an ultrasonic probe adapted measure and control the transmural depth of the device into the cardiac tissue;

FIG. **4** is another detailed view illustrating multiple cryotreatment devices coupled together using a coupling member;

FIG. **5** is a view of a cryotreatment device in accordance with an exemplary embodiment of the present invention, wherein the cryotreatment device includes a linear array of ablation tips;

FIG. **6** is a partial cross-sectional view of a cryotreatment device in accordance with an exemplary embodiment of the present invention, wherein the cryotreatment device includes several retractable cryogenic tips configured to form a circumferential line of conduction block within the heart; and

FIG. **7** is a partial cross-sectional view of a cryotreatment device in accordance with another exemplary embodiment of the present invention, wherein the cryotreatment devices includes an enlarged distal portion with retractable ablation tips.

DETAILED DESCRIPTION OF THE INVENTION

The following description should be read with reference to the drawings, in which like elements in different drawings are numbered in like fashion. The drawings, which are not necessarily to scale, depict selected embodiments and are not intended to limit the scope of the invention. Although examples of construction, dimensions, and materials are illustrated for the various elements, those skilled in the art will recognize that many of the examples provided have suitable alternatives that may be utilized.

FIG. **1** is an illustrative view of a cryotreatment device **10** in accordance with an exemplary embodiment of the present invention for inducing controlled necrosis at one or more pre-mapped target sites within the heart. A guide wire **12** inserted percutaneously into the femoral or jugular veins is shown advanced through the septal wall **14** and into the upper chambers **16**,**18** of a heart **20**. Using known manipulation techniques in the art, guidewire **12** can be advanced to a location distal a target site **22** determined to cause electrical interference with one or more downstream arrythmogenic foci **24**. A guide catheter **26** sufficiently sized to receive cryotreatment device **10** can be used to advance the cryotreatment device **10** to a location at or near the target site **22**.

Arrhythmias such as atrial flutter, atrial fibrillation and ventricular tachycardia are typically caused when abnormal regions of the heart transmit aberrant electrical signals vis-a-vis arrythmogenic foci. To treat such arrhythmias, a cryotreatment device in accordance with the present invention can be inserted into cardiac tissue at a pre-mapped target site and cooled to a temperature of about −40 to −100° C. to induce necrosis at one or more locations **28**,**30**,**32**,**34** within the heart, such as the pulmonary vein **36**. The cryotreatment device can be inserted at the various locations **28**,**30**,**32**,**34** to form a line of conduction block that prevents certain electrical signals from being sent from the foci points **24**. In necrotizing the cardiac tissue at several locations, thereby forming a line of conduction block in the pulmonary vein **36**, the transmission of aberrant signals believed to cause the arrhythmia can be reduced or in some cases altogether eliminated.

FIG. **2** is a partial cross-sectional view of the cryotreatment device **10** of FIG. **1**, showing the distal portion **38** of the device **10** in greater detail. In the exemplary embodiment of FIGS. **1**-**2**, cryotreatment device **10** comprises a multiple lumen catheter body **40** having an outer shaft **42** configured to pierce and cool the cardiac tissue, and an inner shaft **44** defining an inner lumen **46** in fluid communication with a cooling fluid. The outer shaft **42** of catheter body **40** may have a transverse cross-sectional area that is substantially circular in shape, extending from a proximal end (not shown) located outside of the patient's body to a transition region **48** on the catheter body **40**. At transition region **48**, catheter body **40** tapers distally to a needle-like ablation tip **50** configured to pierce and contact cardiac tissue.

To cool the distal portion **38** of cryotreatment device **10** to a sufficiently low temperature to induce necrosis when inserted into cardiac tissue, cryotreatment device **10** can be placed in fluid communication with a cooling fluid such as liquid nitrogen, nitrous oxide (N_2O), carbon dioxide (C_2O), chlorodifluoromethane, polydimethysiloxane, ethyl alcohol, chlorofluorocarbons (Freon), or other suitable fluid. The cooling fluid can be delivered in either a liquid or gas state through inner lumen **46**, and injected into the annular space **52** between the outer and inner shafts **42**, **44** through several apertures **54** disposed in the inner shaft **44**. In one embodiment, for example, pressurized liquid nitrous oxide can be fluidly coupled to the inner lumen **46** of catheter body **40**, and ejected through several apertures **54** disposed in the inner lumen **44**. Using the Joule-Thompson cooling effect, the apertures **54** are adapted to act as a throttling element (e.g. a throttling nozzle) for the cryogen, producing isenthalpic cooling as the fluid is expended from a relatively high pressure within the inner lumen **46** to a lower pressure as it enters the annular space **52**. As the cryogenic fluid expands as it passes through the apertures **54**, it transitions to a gas and impinges upon the interior wall **56** of the outer shaft **42** cooling the distal portion **38** of the catheter body **40**. This temperature drop is then thermally transferred through the catheter body **40** and into the surrounding cardiac tissue **58**, inducing necrosis at the target site **22**. The cryogenic fluid is subsequently returned through annular lumen **52** to the proximal end of the device **10**.

The number of apertures **54** can be varied to provide a desired temperature decrease to the distal portion **38** of the catheter body **40**. The type of cryogen used and the pressure and/or volume at which the cryogen is delivered through the inner lumen **46** can also be selected to impart a particular cooling characteristic to the device **10**, as desired. In the exemplary embodiment of FIGS. **1**-**2**, cryotreatment device **10** includes several equidistantly spaced apertures **54** configured to provide uniform cooling through the distal portion **38** of the catheter body **40**. It should be recognized, however, that the apertures **54** could be placed at any number of strategic locations, at either equidistant or non-equidistant intervals, to direct the cryogenic fluid to a particular location within the device **10**.

The outer and inner shafts **42**, **44** of cryotreatment device **10** may be fabricated from materials having certain desirable flexibility and thermodynamic properties. For example, the outer and inner shafts **42**, **44** may each be formed of a super-elastic material such as nickel-titanium alloy (Nitinol) to permit the cryotreatment device **10** to be inserted through relatively tortuous locations of the body without kinking. Other suitable biocompatible materials such stainless steel or a polymer/metal composition may also be utilized, depending on the particular application.

Referring now to FIG. **3**, methods of using cryotreatment device **10** will now be described in the context of a cryosurgical procedure to necrotize cardiac tissue **58** within a body lumen such as a pulmonary vein **36**. Cryotreatment device **10** can be inserted through a previously positioned guide catheter **26** and advanced to a pre-mapped target site **22** within the heart believed to transmit aberrant electrical signals to one or more relay points. As shown in FIG. **3**, needle-like ablation tip **50** of device **10** can be configured to pierce and contact the cardiac tissue **58** of pulmonary vein **36**, allowing the distal portion **38** of catheter body **40** to be inserted into the cardiac tissue **58**. A curved portion **60** on the catheter body **40** may be adapted to orient the needle-like ablation tip **50** in a direction substantially perpendicular to the tissue wall **58**.

In one aspect of the present invention, cryotreatment device **10** can be configured to measure and control the transmural depth at which the device is inserted into the cardiac tissue **58**. Controlled insertion of the needle-tip ablation tip **50** into the cardiac tissue **58** prevents distension of the vein **36** from occurring, and prevents the ablation of cardiac tissue not necessary to form the conduction block. Controlled insertion of the needle-like ablation tip **50** into the cardiac tissue **58** also ensures that the cryotreatment device **10** is inserted at a sufficient depth to form the desired conduction block.

An ultrasonic probe **62** or other measurement device may be utilized to measure the precise depth at which cryotreatment device **10** is inserted into the cardiac tissue **58**. The ultrasonic probe **62** can be coupled to catheter body **40** a predetermined distance from the needle-like ablation tip **50**, and engaged to acoustically measure the depth at which the distal portion **38** is inserted into the cardiac tissue **58**. The ultrasonic probe **62** may be coupled to the catheter body **40**, or may be formed as a separate element that can be advanced along the catheter body **40** and positioned proximal the cardiac tissue **58**. In one exemplary embodiment, the ultrasonic probe **62** may act as a guiding member for the device **10**, eliminating the need for a separate guide catheter. Those of skill in the art will readily recognize that other suitable devices for measuring the insertion depth of the cryotreatment device **10** may be employed, including, for example, the use of an optical probe, acoustic reflective coatings, distal bipolar electrodes, or through the use radiographic techniques such as fluoroscopic marker bands.

In operation, a fluid controller or other similar device can be coupled to the proximal end of the cryotreatment device **10** and used to inject a controlled flow of cryogenic fluid (e.g. liquid N_2O) through the inner lumen **46**. One or more temperature sensors **39** on the distal portion **38** of catheter body **40** may also optionally be used to monitor the temperature of the device **10** and adjust the flow rate via the fluid controller, as necessary. An insulated sleeve **64** surrounding the catheter body **40** may be utilized to thermally isolate the catheter body **40** proximal the distal portion **38** to prevent ablating other areas of the body.

In certain embodiments, the cryotreatment device may include a coupling member configured to couple multiple ablation tips together in an array. As shown in FIG. **4**, for example, a coupling member **66** can be used to connect multiple cryotreatment devices **10** together, forming a linear array of needle-like ablation tips **50** that, when thermally cooled via a cryogenic fluid, create a line of contiguous conduction block along the cardiac tissue **58** at the target site **22**. The coupling member **66** can be configured to couple together any number of cryotreatment devices together in any desired array or pattern. The multiple cooling members **10** applied in a sequential cooling method will allow the lesions to be made in a stitched like fashion to ensure contiguous connection of all the lesions. The method of stitching is accomplished by moving one needle **50** while the other needle **50'** is anchored and froze into the tissue. The sequence of operation would be as follows:

1. Insert two needles at start point and apply maximum freeze;
2. Thaw the proximal needle and reduce temperature on distal needle;
3. Retract proximal needle and rotate around anchored distal needle;
4. Apply maximum cooling on both needles and repeat steps 2-4.

FIG. **5** is a view of a cryotreatment device **68** in accordance with another exemplary **20** embodiment of the present invention. Cryotreatment **68** comprises a catheter body **70** having several linearly disposed ablation tips **72** along a distal portion **74** that, when placed into fluid communication with a cryogenic cooling fluid, are configured to form a line of conduction block within a target site of the heart. Each ablation tip **72** may be configured similar to tip **50** described above, having a needle-like shape configured to pierce and contact the cardiac tissue when inserted. The number of needles **72** and lumens **76** may be the same as shown, or may be as few as two needles **72** for any number of lumens **76** in the method previously described. An inner lumen **76** in fluid communication with a source of pressurized cryogen at or near the proximal end of the device **70** is configured to cool each ablation tip **72** in a manner similar that described above with respect to cryotreatment device **10**. The cryotreatment device **70** may also optionally include an ultrasonic probe or other measurement means (not shown) for measuring the precise depth at which the ablations tips **72** are transmurally inserted into the cardiac tissue. An insulation layer **78** surrounding the catheter body **70** thermally insulates the body **70** from ablating other areas of the body.

To form a line of conduction block within a target site of the heart, ablation tips **72** can be aligned with a portion of the cardiac tissue believed to transfer the aberrant electrical signal(s) to one or more downstream relay points, and inserted into the tissue at a controlled depth. A pressurized cryogenic fluid can be delivered through the catheter body **70**, causing the ablation tips **72** on the distal portion **74** to undergo a temperature drop to a temperature of about −40 to −100° C., inducing necrosis in the surrounding cardiac tissue.

The destruction of more tissue than is necessary to form the conduction block may be mitigated through the use of a series of smaller ablation tips. Moreover, the number, shape and arrangement of the ablation tips may be varied in accordance with the particular application. In certain applications, for example, a cryotreatment device in accordance with the present invention may be configured to form a circumferential line of conduction blocks at a target site within the heart.

In one exemplary embodiment shown in FIG. **6**, a cryotreatment device **80** in accordance with the present invention may include a catheter body **82** having several needle-like ablation tips **84** on distal end **86** that, when thermally cooled via a supplied source of cryogenic fluid, form a circumferential line of conduction block at a target site within the heart (e.g. about a pulmonary vein). Cryotreatment device **80** may comprise an outer shaft **88**, and an inner shaft **90** disposed within the outer shaft **88**. The inner shaft **90** can be configured to deliver a pressurized source of cryogenic fluid such as liquid nitrogen or N_2O through aperture **92** towards the interior surface **94** of distal end **86**, causing the interior surface **94** of the distal end **86** of catheter body **82** to cool and conduct heat.

Each of the needle-like ablation tips **84** can be configured to retract through several openings **96** disposed on the distal end **86** of the catheter body **82**. A control wire **98** extending proximally from each ablation tip **84** to a location outside of the patient's body may be used to retract each tip **84** through its respective opening **96**, allowing the operator to adjust the precise depth at which the tip **84** is inserted the cardiac tissue. A flange **100** coupled to each ablation tip **84** prevents the tip **84** from being pulled proximally through opening **96** as control wire **98** is retracted. As with any of the other embodiments described herein, an ultrasonic probe or other suitable device can be utilized to measure and, if necessary, control the penetration depth of the ablation tips **84** within the tissue.

In use, cryotreatment device **80** can be advanced to a target site within the heart, and, with the ablation tips **84** initially in a fully deployed position, inserted into the cardiac tissue. Once the device **80** is inserted into the tissue, the operator can retract the control wire **98** proximally a distance, causing the ablation tips **84** to retract from within the tissue a slight distance (e.g. 0.5-3.0 cm). An ultrasonic probe or other suitable device may be used to measure the precise depth at which the ablation tips **84** are inserted into the cardiac tissue. At the desired depth, a pressurized flow of cryogen is then delivered through the device, causing the distal end **86** of the device, including the ablation tips **84**, to cool to a temperature of about −40 to −100° C., forming a circumferential line of conduction block within the body.

FIG. **7** is a partial cross-sectional view of a cryotreatment device **102** in accordance with another exemplary embodiment of the present invention. Cryotreatment device **102** comprises an outer shaft **104** having a proximal portion (not shown), a distal portion **106**, and an inner lumen **108** in fluid communication with a cooling fluid such as liquid N_2O. The distal portion **106** of cryotreatment device **102** may be enlarged slightly, orienting several retractable needle-like ablation tips **110** in a wider radial array, permitting the formation of a circumferential line of conduction block at larger target sites. A control wire **112** operatively coupled to each ablation tip **110** can be utilized to adjust the transmural depth of the tip **110** into the cardiac tissue. A flanged portion **114** on each ablation tip **110** prevents the operator from pulling the ablation tip **110** proximally through the tip openings **116** on the distal portion **106** of the outer shaft **104**.

Having thus described the several embodiments of the present invention, those of skill in the art will readily appreciate that other embodiments may be made and used which fall within the scope of the claims attached hereto. Numerous advantages of the invention covered by this document have been set forth in the foregoing description. It will be understood that this disclosure is, in many respects, only illustrative. Changes may be made in details, particularly in matters of shape, size and arrangement of parts without exceeding the scope of the invention.

What is claimed is:

1. A medical device for inducing controlled necrosis at a target site within the body, comprising:

an elongated member having a proximal portion, a distal portion, and a lumen therein providing a fluid path, wherein the distal portion is radially enlarged; and

an ablation tip array comprising a plurality of ablation tips in communication with said fluid path, wherein the ablation tips are radially arranged about the radially enlarged distal portion of said elongated member and are configured to contact and ablate tissue, wherein each of the ablation tips is retractable within the radially enlarged distal portion of said elongated member.

2. The medical device of claim **1**, further comprising a plurality of control wires operatively connected to the plurality of ablation tips to control the transmural depth of the ablation tips into the tissue.

3. The medical device of claim **2**, wherein the transmural depth of each of the ablation tips may be individually controlled.

4. The medical device of claim **3**, wherein said elongated member comprises a plurality of openings in the radially enlarged distal portion through which the ablation tips extend.

5. The medical device of claim **4**, wherein each of the ablation tips includes a flange.

6. The medical device of claim **5**, wherein the flange of each ablation tip is distal at least one of the plurality of openings.

7. The medical device of claim **1**, further comprising an ultrasonic sensor mounted so as to move toward the tissue as the ablation tip array moves into the tissue.

8. The medical device of claim **1**, wherein the ablation tips are linearly arranged along an arcuate line on the radially enlarged distal portion of said elongated member.

9. The medical device of claim **1**, wherein the ablation tips are needle-like ablation tips.

10. The medical device of claim **1**, wherein the ablation tip array is configured to form a line of conduction block at said target site.

11. A medical device for inducing controlled necrosis at a target site within the body, comprising:

an elongated member having a proximal portion, a distal portion, and a lumen therein providing a fluid path, wherein the distal portion is radially enlarged; and

an ablation tip array comprising a plurality of ablation tips in communication with said fluid path, wherein the plurality of ablation tips are radially arranged about the radially enlarged distal portion of said elongated member and are configured to form a line of conduction block, wherein each of the plurality of ablation tips is retractable within the radially enlarged distal portion of said elongated member.

12. The medical device of claim **11**, further comprising a plurality of control wires operatively connected to the plurality of ablation tips to control the transmural depth of the ablation tips into the tissue.

13. The medical device of claim **12**, wherein the transmural depth of each of the ablation tips may be individually controlled.

14. The medical device of claim **13**, wherein said elongated member comprises a plurality of openings in the radially enlarged distal portion through which the ablation tips extend.

15. The medical device of claim **14**, wherein each of the ablation tips includes a flange.

16. The medical device of claim **15**, wherein the flange of each ablation tip is distal at least one of the plurality of openings.

17. The medical device of claim **11**, further comprising an ultrasonic sensor mounted so as to move toward the tissue as the ablation tip array moves into the tissue.

18. The medical device of claim **11**, wherein the ablation tips are linearly arranged along an arcuate line on the radially enlarged distal portion of said elongated member.

19. The medical device of claim **11**, wherein the ablation tips are needle-like ablation tips.

20. The medical device of claim **11**, further comprising a guiding member configured to transport said elongated member to the target site.

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